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09/981,167	10/17/2001	Peter Gadsby	TCO2-101US	5605
23122	7590	07/02/2004	EXAMINER	
RATNERPRESTIA			DROESCH, KRISTEN L	
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VALLEY FORGE, PA 19482-0980			3762	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/981,167

Applicant(s)

GADSBY ET AL.

Examiner

Kristen Droesch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 3/25/04 (response).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-26 and 28-34 is/are rejected.
- 7) ☒ Claim(s) 11 and 27 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/17/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 2, 16, 20-25, 28, and 31 are rejected under 35 U.S.C. 102(e) as anticipated by Katzenmaier et al. (6,356,779).
4. Claims 1, 3-9, 12, 15, 19, and 32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Katzenmaier et al. (6,356,779).

Regarding claims 1-3, 16, 19, and 32, Katzenmaier et al. shows a pair of medical electrodes comprising a first electrode (52) including a first electrode member (16, 36) having a first top face and a first bottom face; a first electrically conductive coating (17, 37) of a first metal and a first amount of metal chloride disposed on the first bottom face; a first electrically conductive gel pad (18, 38) disposed on said first coating including a

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first buffer; and a second electrode (50) including a second electrode member (16, 36) having a second top face and a second bottom face; a second electrically conductive coating (17, 37) of a second metal and a second amount of metal chloride disposed on the second bottom face, the second amount of metal chloride being greater than the first amount of metal chloride; a second electrically conductive gel pad (18, 38) disposed on said second coating including a second buffer (Figs. 1-3; Col. 4, line 38-Col. 6, line 20; Col.13, lines 21-38).

Although Katzenmaier et al. fails to specifically point out that the buffer is contained in the gel pad (18, 38), it is inherent that the buffer is contained in the gel pad since it is the only portion of the Katzenmaier et al. electrode capable of containing a buffer.

Assuming arguendo that the Katzenmaier et al. reference does not teach the second amount of metal chloride is greater than the first amount of metal chloride, attention is directed to Col.13, lines 21-38 of the Katxenmaier et al. reference. Katzenmaier et al. teaches altering each of the electrodes (50, 52) so that one electrode (50) can have a negative polarity for placement on the apex of the chest, and the second electrode (52) to have a positive polarity. Katzenmaier et al.. teaches that each of the electrodes can be optimized to provide the positive and negative polarities of the electrodes by optimization in terms of the ratio of silver to silver chloride. Based on basic chemistry, if the ratio of silver to silver chloride is more than 1:1 there will be more silver ions  $\text{Ag}^{+1}$  in the silver chloride  $\text{AgCl}$  solution, and it will have a positive polarity, while if the ratio of silver to silver chloride is less than 1:1 there will be fewer silver ions  $\text{Ag}^{+1}$  in the silver chloride  $\text{AgCl}$  solution, and it would be less positive and more negative in

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comparison to the solution having a ratio of silver to silver chloride greater than 1:1. One with ordinary skill in the art would optimize the first electrode (52) to have a positive polarity and the second electrode (50) to have a negative polarity by either increasing the ratio of silver to silver chloride in the first electrode (52) or by decreasing the ratio of silver to silver chloride in the second electrode (50) in order to make the first electrode have a positive polarity by increasing the number of silver ions  $\text{Ag}^{+1}$  in the silver chloride  $\text{AgCl}$  solution. In either case, the second electrode (50) will have more metal chloride than the first electrode (52).

Given the Katzenmaier et al. teaching and an understanding of basic chemistry, it would have been obvious to one with ordinary skill in the art at the time the invention was made to optimize the electrodes to provide one electrode with a positive polarity and one with a negative polarity by optimizing the ratio of silver to silver chloride of the positive polarity electrode and the negative polarity electrode so that the second electrode has a second amount of metal chloride greater than the first amount of metal chloride in the first electrode.

Regarding claims 4, and 20, Katzenmaier et al. shows first and second insulative sheets (11, 12, 32) disposed on the first and second top faces (Figs. 1-3; Col. 4, line 38-Col. 6, line 20).

With respect to claims 5, and 21, Katzenmaier et al. shows first and second electrical connectors (22) in contact with the first and second top faces (Figs. 1-2).

Regarding claims 6, and 22, Katzenmaier et al. shows first and second removable release carrier sheets (20, 40) disposed on the first and second gel pads (Figs. 1-2).

With respect to claims 7-8, and 23-24, Katzenmaier et al. shows the first and second metal are silver, and the metal chloride is silver (Col. 5, lines 5-60).

Regarding claims 9 and 25, Katzenmaier et al. shows the first electrode (52) is a positive electrode and the second electrode (50) is a negative electrode (Col. 13, lines 21-38).

With respect to claims 12 and 28, Katzenmaier et al. shows the first and second electrode are electrically conductive carbon filled (16, 36) polymers (11, 12, 32) (Col. 4, lines 51-64; Col. 5, lines 43-48) and the first and second gel pads comprise a skin compatible hydrogel (Col. 5, line 66-Col. 7, line 30).

With respect to claims 15, and 31, Katzenmaier et al. shows the first and second coating is an ink coating (Col. 5, lines 57-60).

5. Claims 1-8, 10, 12-16, 19-24, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari (5,824,033) in view of Katzenmaier et al. (6,356,779).

With respect to claims 1-3, 16, 19, and 32, Ferrari shows a pair of medical electrodes comprising a first electrode (10) including a first electrode member (21) having a first top face and a first bottom face; a first electrically conductive coating (23) of a first metal and a first amount of metal chloride disposed on the first bottom face; a first electrically conductive gel pad (25) disposed on said first coating and a second electrode (10) including a second electrode member (21) having a second top face and a second bottom face; a second electrically conductive coating (23) of a second metal and a second amount of metal chloride disposed on the second bottom face; a second electrically conductive gel pad (25) disposed on said second coating. Although Ferrari fails to show the first and second conductive gel pads comprise first and second buffers

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and the second amount of metal chloride is greater than the first amount of metal chloride, attention is directed to Katzenmaier et al. which shows that the ratio of silver to silver chloride and the buffers (in the conductive gel pad/adhesive) can be optimized to provide the best possible conductive layers for negative polarity of the first electrode and positive polarity for the second electrode for specific application to the body. For further explanation see paragraph 3. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the gel pads of Ferrari to comprise buffers, and to modify the conductive coatings of Ferrari to have more metal chloride in one electrode than the other as Katzenmaier et al. teaches in order to provide the best possible conductive layers for negative polarity of the first electrode and positive polarity for the second electrode for specific application to the body.

Although Ferrarri and Katzenmaier et al. fail to specifically point out that the buffer is contained in the gel pad, it is inherent that the buffer of Katzenmaier et al. is contained in the gel pad since it is the only portion of the electrode capable of containing a buffer.

Regarding claims 4, and 20, Ferrarri shows first and second insulative sheets (33) disposed on the first and second top faces (Figs. 1-2).

With respect to claims 5, and 21, Ferrarri shows first and second electrical connectors (35a) in contact with the first and second top faces (Fig. 1).

Regarding claims 6, and 22, Ferrarri shows first and second removable release carrier sheets (31) disposed on the first and second gel pads (Figs. 1-2).

With respect to claims 7-8, and 23-24, Ferrarri shows the first and second metal are silver, and the metal chloride is silver (Col. 4, lines 25-42).

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Regarding claims 10, 14, 26, and 30, Ferarri shows the first and second electrical connectors comprising conductive fanned wires of copper–nickel coated fibers (Col. 6, line 46-Col. 7, line 56).

With respect to claims 12 and 28, Ferrarri shows the first and second electrode are electrically conductive carbon filled polymers (Col. 4, line 59 - Col. 5, line 4) and the first and second gel pads (25) comprise a skin compatible hydrogel (Col. 3, lines 48-60).

Regarding claims 13, and 29, Ferrarri shows the first and second electrode members each have an area of at least 50 cm<sup>2</sup> (Col. 4, lines 42-58).

With respect to claims 15, and 31, Ferrarri shows the first and second coating is an ink coating (Col. 4, lines 24-42).

6. Claims 17-18, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ferrari (5,824,033) and Katzenmaier et al. (6,356,779) as applied to claims 16 and 32 above. Ferrari and Katzenmaier et al. disclose the claimed invention except for the first and second buffers comprising piprizene dihydrochloride in combination with glycylglycine or piprizene dihydrochloride in combination with sodium hydrogen maleate. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify buffers as taught by Katzenmaier et al. with piprizene dihydrochloride in combination with glycylglycine or piprizene dihydrochloride in combination with sodium hydrogen maleate, since applicant has not disclosed that these particular buffers provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any buffer such as the buffer taught by Ferrari and Katzenmaier et al. for optimizing the electrodes to each be anodal and cathodal.



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7. Claims 10, 14, 26, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzenmaier et al. (6,356,779) in view of Ferrari (5,824,033).

Katzenmaier et al. is as explained before. Although Katzenmaier et al. fails to show the first and second electrical connectors comprising conductive fanned wires of copper–nickel coated fibers, attention is directed to Ferrari who teaches electrical connectors comprising conductive fanned wires of copper–nickel coated fibers (Col. 6, line 46-Col. 7, line 56). Ferrari teaches that utilizing fanned wires increases the contact area, the use carbon fibers is advantageous because they are X-ray transparent, and the coating of copper-nickel provides electrical conductivity. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the connectors of Katzenmaier et al. with connectors comprising conductive fanned wires of copper–nickel coated fibers as Ferrari teaches in order for the electrical connector to be conductive, yet X-ray transparent with an increased contact area.

8. Claims 13, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzenmaier et al. (6,356,779) in view of Ferrari (5,824,033). Katzenmaier et al. is as explained before. Although Katzenmaier et al. fails to specifically point out that the first and second electrode members each have an area of at least 50 cm<sup>2</sup>, attention is directed to Ferrari who teaches the ANSI standards recommend the minimum active area of electrodes used for defibrillation should be at least 50 cm<sup>2</sup> (Col. 4, lines 42-58).

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to size the electrodes of Katzenmaier et al. to be 50 cm<sup>2</sup>, since the ANSI standards recommend the minimum active area of electrodes used for defibrillation should be at least 50 cm<sup>2</sup>.

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9. Claims 17-18, and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzenmaier et al. (6,356,779). Katzenmaier et al. discloses the claimed invention except for the first and second buffers comprising piprizene dihydrochloride in combination with glycylglycine or piprizene dihydrochloride in combination with sodium hydrogen maleate. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify buffers as taught by Katzenmaier et al. with piprizene dihydrochloride in combination with glycylglycine or piprizene dihydrochloride in combination with sodium hydrogen maleate, since applicant has not disclosed that these particular buffers provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any buffer such as the buffer taught by Katzenmaier et al. for optimizing the electrodes to each be anodal and cathodal.

***Response to Arguments***

10. Applicant's arguments filed 3/25/04 have been fully considered but they are not persuasive.

Applicant's arguments regarding the rejection of claim 1 and those dependent thereon have been addressed in paragraph 3.

The examiner disagrees with applicant's arguments regarding the rejection of claim 2 and those dependent thereon. Applicant contends that Katzenmaier et al. does not show a first buffer and a second buffer. Katzenmaier et al. shows optimization of the **electrodes** in terms of *inter alia* **buffers**. Katzenmaier et al. uses the plural form of the word buffer, which would mean that there are two buffers in each electrode or that each electrode has a buffer.

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Applicant also argues that one skilled in the art would assume that the Katzenmaier et al. reference was referring to the use of the same buffer for both electrodes. Applicant's claims do not state that the first buffer is different than the second buffer.

Applicant also argues that the Katzenmaier et al. reference does not disclose using the buffers in the conductive gel pad. The claims do not state that the buffers are *in* the conductive gel pad. Furthermore, it is inherent that the buffers are located in the gel pad since there are no other portions of the Katzenmaier et al. electrodes that would be capable of containing buffers.

#### ***Allowable Subject Matter***

11. Claims 11 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

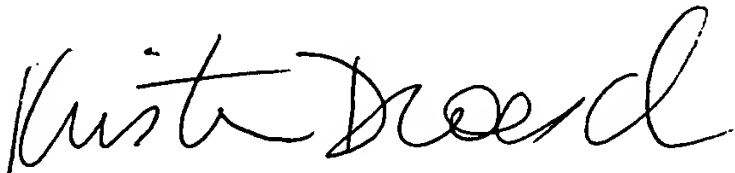
#### ***Conclusion***

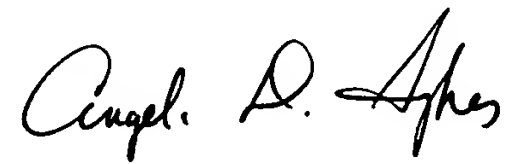
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on 10:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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